



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,248	03/26/2001	Peter Baumann	89491/201	8759

7590

02/28/2002

Richard J. Warburg, Esq.
FOLEY & LARDNER
28th Fl.
402 West Broadway
San Diego, CA 92101-3542

EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
----------	--------------

1634

DATE MAILED: 02/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/816,248

Applicant(s)

BAUMANN ET AL.

Examiner

Carla Myers

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1634

RESTRICTION

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-5, drawn to human POT-1 proteins, classified in Class 530, subclass 350.
- II. Claims 6-11, drawn to *Saccharomyces* POT-1 proteins, classified in Class 530, subclass 350.
- III. Claims 12, 13 and 18, drawn to nucleic acids encoding human POT-1 proteins, classified in Class 536, subclass 23.5.
- IV. Claims 14-18, drawn to nucleic acids encoding *Saccharomyces* POT-1 proteins, classified in Class 536, subclass 23.7.
- V. Claims 19-21, drawn to antibodies, classified in Class 530, subclass 387.
- VI. Claims 22-28, drawn to methods to increase the lifespan of a cell by administering a nucleic acid encoding POT1, classified in Class 514, subclass 44.
- VII. Claim 29, drawn to methods for identifying compounds which inhibit binding of POT-1 to DNA, classified in Class 435, subclass 7.1.
- VIII. Claim 30, drawn to a compound that inhibits binding of POT-1 to DNA, classification cannot be determined without additional information regarding the structural properties of the compound.
- IX. Claims 31-34, drawn to a method of decreasing the lifespan of a cell by reducing POT-1 activity, classified, for example, in Class 514, subclass 1; further classification cannot be determined without additional information regarding the means for reducing the lifespan.

Art Unit: 1634

X. Claim 35, drawn to a general method for detecting a POT-1 protein, classified in Class 435, subclass 7.1

XI. Claim 36, drawn to a general method for detecting POT-1 nucleic acid, classified in Class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct in structure and physicochemical properties. Invention I is drawn to human POT-1 proteins, whereas invention II is drawn to *Saccharomyces* POT-1 proteins. The amino acid sequence of human and *Saccharomyces* POT-1 proteins differ from one another and are structurally distinct chemical compounds. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14.

Inventions I and III are patentably distinct in structure and physicochemical properties. Invention I is drawn to human POT-1 proteins, whereas invention III is drawn to human POT-1 nucleic acids. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins of invention I do not require the particular products of the

Art Unit: 1634

nucleic acids of invention III since the proteins of invention I can be isolated from natural sources or chemically synthesized.

Inventions I and IV are patentably distinct in structure and physicochemical properties. Invention I is drawn to human POT-1 proteins, whereas invention IV is drawn to *Saccharomyces* POT-1 nucleic acids. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. In addition, the nucleic acids of invention IV do not encode for the human proteins of invention I. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies.

Inventions I and V are patentably distinct in structure in that the proteins of invention I have a different amino acid sequence as compared to the antibodies of invention V. Furthermore, the products of invention I and V are utilized in different methodologies, such that the proteins may be utilized in ligand binding assays and the antibodies may be used in therapeutic methods. Synthesis of the antibodies of invention V does not require the particular products of the proteins of invention I since the antibodies of invention V can be isolated from natural sources.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of invention I are not specifically required to practice the method of invention V. Furthermore,

Art Unit: 1634

the proteins of invention I can be used in materially different methods, such as the generation of antibodies.

Inventions I and VII, I and IX and I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of invention I can be used in a materially different process, such as for generating antibodies.

Inventions I and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of invention I are structurally and functionally distinct from the compounds of invention VIII and may be used in materially different processes such as the generation of or detection of antibodies.

Inventions I and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of invention I are not required to practice the method of invention XI.

Inventions II and III are patentably distinct in structure and physicochemical properties. Invention II is drawn to *Saccharomyces* POT-1 proteins, whereas invention III is drawn to human POT-1 nucleic acids. Because nucleic acids are composed of nucleotides and proteins are

Art Unit: 1634

composed of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins of invention II do not require the particular products of the nucleic acids of invention III since the proteins of invention II can be isolated from natural sources or chemically synthesized and because the human POT-1 nucleic acids of invention III do not encode for the *Saccharomyces* proteins of invention II.

Inventions II and IV are patentably distinct in structure and physicochemical properties. Invention II is drawn to *Saccharomyces* POT-1 proteins, whereas invention IV is drawn to *Saccharomyces* POT-1 nucleic acids. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. The nucleic acids of invention IV are not required to produce the proteins of invention II because the proteins can be chemically synthesized or isolated from nature.

Inventions II and V are patentably distinct in structure in that the proteins of invention II have a different amino acid sequence as compared to the antibodies of invention V. Furthermore, the products of invention II and V are utilized in different methodologies, such that the proteins may be utilized in ligand binding assays and the antibodies may be used in therapeutic methods.

Art Unit: 1634

Synthesis of the antibodies of invention V does not require the particular products of the proteins of invention I since the antibodies of invention V can be isolated from natural sources.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of invention II are not specifically required to practice the method of invention V. Furthermore, the proteins of invention II can be used in materially different methods, such as the generation of antibodies.

Inventions II and VII, II and IX and II and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of invention II can be used in a materially different process, such as for generating antibodies.

Inventions II and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of invention II are structurally and functionally distinct from the compounds of invention VIII and may be used in materially different processes such as the generation of or detection of antibodies.

Art Unit: 1634

Inventions II and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of invention I are not required to practice the method of invention XI.

Inventions III and IV are patentably distinct in structure and physicochemical properties. Invention III is drawn to human POT-1 nucleic acids, whereas invention IV is drawn to *Saccharomyces* POT-1 nucleic acids. The nucleotide sequence of human and *Saccharomyces* POT-1 nucleic acids differ from one another and are structurally distinct chemical compounds. These nucleotide sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14.

Inventions III and V and III and V are patentably distinct in structure and physicochemical properties. Inventions III and IV are drawn to nucleic acids, whereas invention V is drawn to antibodies. Because nucleic acids are composed of nucleotides and antibodies are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while antibodies may be utilized in ligand binding assays or to generate antibodies. The nucleic acids of inventions III and IV are not required to produce the

Art Unit: 1634

antibodies of invention V and the antibodies of invention V can be chemically synthesized or isolated from nature.

Inventions III and VI and IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of invention III and IV can be used in a materially different process, such as for synthesizing nucleic acids or proteins or for methods of detecting nucleic acids.

Inventions III and VII and inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of inventions III and IV are not specifically required to practice the method of invention VII. Furthermore, the nucleic acids of inventions III and IV can be used in materially different methods, such as for synthesizing nucleic acids or proteins or for methods of detecting nucleic acids.

Inventions III and VIII and inventions IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP

Art Unit: 1634

§ 808.01). In the instant case, the nucleic acids of inventions III and IV are structurally and functionally distinct from the compounds of invention VIII.

Inventions III and X and IV and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention III and IV are not required to practice the method of invention X.

Inventions III and XI and IV and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of invention III and IV can be used in a materially different process, such as for synthesizing nucleic acids or proteins or for therapeutic purposes.

Inventions V and VI, V and IX and V and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibodies of invention V are not required to practice the method of inventions VI, IX or XI.

Art Unit: 1634

Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of invention V can be used in a materially different process, such as for isolating or detecting protein.

Inventions V and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibodies of inventions V are structurally and functionally distinct from the compounds of invention VIII.

Inventions V and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of invention V can be used in a materially different process, such as for therapeutic purposes.

Inventions VI, VII, IX, X and XI are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Art Unit: 1634

In the instant case, the different inventions are drawn to distinct methods, each requiring different reagents, involving different method steps and having different objectives.

Inventions VII and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product can be made by a materially different process. That is, the product may be obtained from any source and does not need to be first identified by the screening method of invention VII.

Inventions VIII and IX, VIII and X and VIII and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the compounds of invention VIII are not specifically required to practice the methods of inventions IX, X or XI.

2. It is noted that the claims of groups V-XI are drawn generically to methods which involve a "POT-1" nucleic acid or protein. To the extent that these claims are intended to include specific POT-1 nucleic acids and proteins, Applicant is required to select a single POT-1 species, i.e. human POT-1 or *Saccharomyces* POT-1.

3. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-IX require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.
4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
6. A telephone call was made to Brian Lathrop on February 6, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made because Applicant requested that the restriction be made in writing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

February 25, 2001


CARLA J. MYERS
PRIMARY EXAMINER